ABBOTT

Corporate Regulatory Affairs

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March 21, 2000

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane (HFA-305)
Room 1061
Rockville, MD 20852

RE: Requirement for Redacted Version of Substantially-Equivalent Premarket Notification
[Docket Number 99N-4784]

Dear Sirs or Madams:

Abbott Laboratories submits the following remarks in response to the Agency's request for comments on the above-named subject and docket. Abbott is an integrated worldwide manufacturer of healthcare products employing more than 56,000 people and serving customers in more than 130 countries.

SUMMARY

Abbott generally agrees with FDA's proposal to better utilize its resources as described in this proposal. The Agency should be commended for trying to improve its resource utilization by way of this proposal. Two aspects of the proposal are of concern: (1) Eliminating the 510(k) statement as an alternative to submitting a redacted 510(k) within 30 days of a substantially equivalent determination, and, (2) FDA's intent "to make all redacted 510(k)s available through the Internet, regardless of whether a FOIA request has been received" (64 FR 71350). We encourage the Agency to maintain the competitive nature of the medical device industry by continually striving to protect confidential data. This item deserves additional attention throughout the proposal and rulemaking process.

I. INTRODUCTION

Currently, companies rely on the FDA to conceal or redact data in regulatory submissions. This proposal appears to address the current state of affairs while also increasing the FDA's overall efficiency.

II. RECOMMENDATIONS

We recommend that the FDA consider various competitive and regulatory alternatives.

1. Protect Industry Competitiveness

A. Use of the 510(k) Statement. We request that FDA allow applicants to use the 510(k) statement as an alternative to submitting a redacted 510(k) within 30 days of clearance. In addition, we request that FDA limit Internet postings to Freedom of Information Act (FOIA) requested premarket notifications in accordance with FOIA.

B. We request that FDA formally publish the results of its consultations with the U.S. Department of Justice on this matter.

2. Encourage Better Use of FDA Resources

If the FDA goes forward with this proposal and does indeed gain additional resources as a result, we respectfully request that these resources be applied to the submissions process. The rationale for this request is that FDAMA has mandated significant changes in the submissions area including new types of submissions, the use of third party reviewers and an increased use of standards.

3. Consult with Industry

Industry as a whole should have an appropriate voice in what affects its business. We request that the Agency consult with industry and academia on this proposal since its outcome could adversely affect the overall competitive posture for medical devices. The rationale for this request is based on the novel use of a new global communication technology - the Internet.

4. Moving Forward on This Proposal

The Agency should proceed with this proposal because it provides firms with a mandated opportunity to protect data which is vital for the conduct of business. Specifically, in the past many firms relied on the FDA to redact data contained in a submission. Companies also forgot to protect their data. This proposal changes those practices.

III. DISCUSSION

At the same time that it is possible to support this proposal, a series of comments are appropriate concerning the FDA's statutory authority on this subject.

Direct support from the FD&C Act appears to be lacking. Under the proposed rule, FDA relies primarily on two statutes to establish its duty to disclose agency records. These two statues are the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Administrative Procedure Act (APA). With the exception of section 513(i)(3), the FD&C Act does not require Agency disclosure of records. Section 513(i)(3) of the FD&C Act imposes upon the Agency the duty to make available to the public a "510(k) Summary," which is a subsection of a premarket notification.

Alternatively, the FD&C Act imposes upon the premarket notification applicant the duty to state that information contained in a "510(k) Summary" will be made available upon request (i.e. 510(k) statement). Neither the FDA's duty to make a "510(k) Summary" available to the public or the applicant's duty to provide a statement to make such information available is the subject of this proposed rule.

Section 5 U.S.C. 552 of the APA, commonly referred to as the Freedom of Information Act or FOIA sets forth the Agency's responsibilities in making information available to the public. Under these provisions, federal agencies are to make available to the public the following types of information: descriptions of the agency organization, methods for obtaining decisions or information, requirements of all formal and informal procedures available, rules of procedure, substantive rules of law, general policy or interpretations adopted by the agency, amendments, revision or repeal of such matters, administration staff manuals, previously released records if requested frequently, record index, and final opinions.

In addition to these categories of information, federal agencies, upon request for a record, which reasonably describes such record, are to make such record available. The APA, including the Electronic Freedom of Information Act Amendments of 1996, does not require FDA to post non-requested premarket notifications on the Internet nor does it explain FDA's proposal to require submission of redacted premarket notifications when applicants choose to use a "510(k) Statement" as provided by the FD&C Act. Furthermore, FDA fails to address the competitive impact of posting a manufacturer's entire line of premarket notifications on the Internet, when posting such information, in total, discloses business and/or regulatory strategies.

Posting only FOIA requested premarket notifications on the Internet minimizes business concerns, while simultaneously allowing the Agency to adhere to FOIA.

Existing Regulations Allow FDA To Divert Agency Resources

FDA's existing regulations contain a mechanism which will allow FDA to meet its objective. In its proposal, FDA discusses its concern about the amount of time, resources, and effort expended redacting premarket notifications. The Agency further describes how relief from this activity will allow it to divert limited Agency resources to other responsibilities, including support of premarket review and postmarket surveillance.

Existing regulations allow for the use of a "510(k) Statement." Applicants who choose to use a "510(k) Statement" are responsible for responding to requests for information, not FDA. Use of this provision allows FDA to divert limited Agency resources to other responsibilities Additionally, use of the "510(k) Statement" may alleviate FDA from addressing issues raised in the proposed rule, such as release of applicant's copyright material. It may also alleviate FDA from addressing issues that were not discussed in the proposed rule.

Issues not discussed in the proposed rule include: (1) enacting provisions or protections to ensure that the correct redacted premarket notifications are available electronically and (2) ensuring customers, laboratories, and patients do not rely on, as current information, labeling, package inserts, or instrument manuals contained in previously submitted premarket notifications. Often such material is updated, in some cases requiring additional Agency notification (e.g., special 510(k) or traditional 510(k)), while in other cases Agency notification is not required. Depending on the labeling update, reliance on previously submitted information is not in the public's best interest.

Supplementing FDA's proposed rule with an alternative, not requiring submission of a redacted premarket notification when the "510(k) Statement" is used, allows the Agency to divert its limited resources, while at the same provides premarket notification applicants with a mechanism to address publication and safety concerns.

IV. MODIFICATIONS TO THE PROPOSED RULE

For the above-listed reasons, we request modifying the proposed rule as follows:

Add to the end of proposed rule Sec. 807.87(j) "or a 510(k) statement as described in Sec. 807.93(a)(1)(i)."

Delete Sec. 807.93(a)(ii).

Revise Sec. 807.95(f)(1) by beginning the section with "In accordance with Sec. 807.91, commitment to submit a redacted 510(k), and not later than 30 days after..."

These revisions would permit applicants to use the 510(k) statement as an alternative to submitting a redacted 510(k). Additionally, we request FDA to reconsider its intent to publish all 510(k)s on the Internet whether or not a FOIA request has been made.

V. IMPLEMENTATION

Abbott recommends that the promulgation of a final rule on this subject be undertaken with an industry-wide educational effort for the following reasons:

A. General educational purposes. Any public seminars on this rule and its implications will help everyone concerned. For example, the FDA could hold one or more workshops on expectations of the proposed regulation. Such activities could be carried out with the support of HIMA, FDLI or other scientifically oriented trade association. The Agency could also discuss this effort on one of the upcoming FDA telecasts.

B. Publicity. The impact of this rule may affect regulatory practices and expectations of manufacturers. By carrying out these seminars, the Agency can publicize and prepare all concerned for the new requirements.

C. Clarity. Such presentations will serve to clarify regulatory expectations and interpretations.

VI. SPECIFIC COMMENTS

We recommend that the Agency formally publish the legal basis for treating copyright material differently depending on who owns that copyright material. FDA suggests it will distinguish between two categories of copyright material; copyright material owned by the applicant and copyright material owned by another person. The Agency plans to implement safeguards to protect the copyright material owned by another person, yet it does not plan to implement the same safeguards to protect the applicant's copyright material.

VII. CLOSING REMARKS

Abbott agrees with FDA's proposal to better utilize its resources as described in this proposal. We believe that the Agency should give full consideration to several choices including eliminating the 510(k) statement as an alternative to submitting a redacted 510(k) within 30 days of a substantially equivalent determination.

Competitive concerns need to be addressed by the Agency and the Justice Department. Broad publication of selected data could hurt many companies. The Agency should actively seek consultation with industry and others on this subject.

If resources are gained as a result of this proposal then the Agency should redirect those resources to the submissions area. FDAMA-driven changes in submissions is the basis for this request.

Thank you for the opportunity to comment on this proposal.

Yours truly,

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